UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE:

MIRENA IUS LEVONORGESTREL-RELATED PRODUCTS LIABILITY LITIGATION (NO. II)

17-MD-2767 (PAE)
17-MC-2767 (PAE)

This Document Relates to All Actions

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

Regulations

PRELIMINARY STATEMENT

Bayer has moved for summary judgment against all Plaintiffs solely on the basis of "general causation." ECF 329, pp. 4-5. Even though this Court compelled Plaintiffs to provide a preview of their response to Bayer's motion before it was filed — a preview that is not permitted by any Rule or any case law — Bayer was still unable to come up with a definition of "general causation," much less an argument grounded in state substantive tort law for why "general causation" is an "essential element," what the standards are for assessing "general causation," or why Plaintiffs' evidence is inadequate. Bayer's Motion for Summary Judgment ("Bayer's Motion") should be denied on that basis alone; a party cannot simply dump an Appendix of case citations on the Court and their opponent, like Bayer did, and expect the work to be done for them.

Even if Bayer had, like an ordinary litigant, made a persuasive argument for why an issue was an essential element of Plaintiffs' claims and how the existing record showed there was no genuine dispute as to that element, summary judgment still could not be entered on this record. This Court eschewed the normal MDL process of full discovery followed by bellwethers and instead restricted the proceedings to whether the Plaintiffs as a whole had admissible expert testimony on the abstract issue of "general causation," which is not an element of any Plaintiffs' claims and would not need to be proven to a jury by any Plaintiff. The Court then made scientific factual findings against the Plaintiffs with no basis in the record, much less an *indisputable* basis, then refused to rule at all on Bayer's experts. The predictable end result is an inadequate record that cannot be squared with the Rules of Civil Procedure, nor with the Fifth and Seventh Amendments. This Court has no record at all on what evidence any of the particular Plaintiffs could use to support their claims, such as differential diagnoses performed by their treating doctors

or analyses of their particular cases by expert witnesses, much less a record that allows it to evaluate if the Plaintiffs can meet the essential element of causation on their claim under the applicable state substantive tort law. The Court similarly has a morass of Bayer's expert testimony that is in the record, interwoven in the Court's prior orders, relevant to this motion, and yet still never ruled upon as admissible or inadmissible.

Pursuant to state law, Plaintiffs are required to demonstrate causation in their own case, not "general causation" in the abstract. This Court's restrictions on the proceedings have resulted in an underdeveloped record in which the Court cannot assess whether *any* Plaintiff could prove causation in their own case, much less a record sufficient for this Court to do as Bayer asks and grant summary judgment against all Plaintiffs in this MDL. Accordingly, pursuant to Fed.R.Civ.P. 56(d), Plaintiffs submit a Declaration it cannot present facts essential to justify their opposition to summary judgment being granted in any of Plaintiffs' particular cases.

Moreover, even if this Court generates a definition of "general causation" for Bayer, grafts a federal "general causation" element onto state substantive tort law, and precludes Plaintiffs from retaining case-specific experts, it will still find a genuine dispute of material fact exists as to "general causation," however defined. Despite this Court's sweeping rejection of the "general causation" opinions of Plaintiffs' experts, the record is ripe with admissible supportive evidence, including Bayer's formal party admissions (ECF 213-2, 213-3); testimony by Bayer's own experts that Bayer's internal epidemiologic data is "consistent with a causal association" (ECF 174, p. 24); testimony by Bayer's corporate designee that it is biologically plausible that sex hormones cause or contribute to intracranial hypertension (ECF 174, pp. 24-25); published, peer-reviewed, and uncontroverted epidemiologic data supporting a causal association between Mirena® and PTC/IH

(ECF 167-64); and pre-litigation peer-reviewed medical literature noting a "well established relationship between PTC and levonorgestrel-releasing implants" (*see, e.g.,* ECF 213, p. 1). Further, as this Court acknowledged in its Order (ECF 320), many of the facts and opinions proffered by Plaintiffs' experts remain conceded or uncontested. The district court's *Daubert* gatekeeping role does not invoke the exclusion of the underlying evidence; indeed, "disputes as to the validity of the underlying data go to the weight of the evidence, and are for the fact-finder to resolve[.]" *Raskin v. Wyatt Co.*, 125 F.3d 55, 66 (2d Cir. 1997).

BACKGROUND

The Judicial Panel on Multidistrict Litigation ("JPML") transferred the present cases to the Southern District of New York for coordinated pretrial proceedings, noting that "[i]ssues concerning general causation, the background science, and Mirena's labeling and regulatory history with respect to the alleged injury will be common to all actions." Transfer Order, MDL No. 2767 (J.P.M.L. Apr. 6, 2017), ECF 1, p. 4. The JPML also cited elimination of duplicative discovery in support of transfer, including "discovery concerning related Bayer contraceptive implants and international discovery from the foreign Bayer defendants[.]" *Id* at 3.

Following transfer to this Court, Bayer urged the Court to address "whether Plaintiffs can provide reliable expert testimony on general causation before conducting full discovery on all other case issues." Bayer's 06/05/2017 Status Letter, pp. 6-7 (ECF 30). Plaintiffs objected to this proposal and requested full pretrial proceedings concerning general causation and liability issues. Plaintiffs' 06/05/2017 Status Letter (ECF 29); Ex. 1 to Parties' Joint 06/05/2017 Letter (ECF 31-1). This Court subsequently ordered prioritization of the issue of "whether plaintiffs have admissible evidence sufficient to establish general causation of the harms alleged" and established

a schedule for general causation litigation. ECF 40, CMO 5, p. 1; ECF 62, ECF 62, CMO 9 ("Order Regarding, *Inter Alia*, General Causation Discovery and Briefing Schedule").

The parties conducted limited discovery related to the issue of general causation before designating general causation experts. *See id.* Following production of expert reports, expert depositions, and briefing on the admissibility of the parties' respective general causation experts, this Court held a sealed Science Day proceeding on April 9, 2018, utilizing non-testifying experts. *See* February 28, 2018 Order, ECF 132. This Science Day was immediately followed by a hearing on admissibility of the parties' general causation experts.

On October 24, 2018, this Court granted Bayer's motion to exclude the testimony of Plaintiffs' seven general causation experts and denied Plaintiffs' motions to exclude Bayer's twelve general causation witnesses as "moot". ECF 321, Opinion and Order. Plaintiffs sought leave to file an interlocutory appeal of the Court's *Daubert* order and Bayer, instead, proposed filing the present motion for summary judgment. *See* ECF 322, 11/09/2018 Joint Letter. This Court granted Bayer's request for summary judgment proceedings. ECF 323, 11/13/2018 Order. This Court then ordered Plaintiffs to produce to Bayer and the Court a letter identifying alleged admissions as to general causation that Plaintiffs believed would defeat summary judgment. ECF 325, 11/19/2018 Order. However, this Court expressly instructed the parties that the letter would not "limit the range of materials on which plaintiffs may rely in their briefing." *Id.* On December 3, 2018, Plaintiffs' made a good faith effort to identify the evidence on which they expected to rely in opposing summary judgment. ECF No. 326, Plaintiffs' 12/03/2018 "Admissions" Letter. Thereafter, Bayer filed its Motion for Summary Judgment on December 14, 2018. ECF 328, 330.

STANDARD OF REVIEW

Summary judgment, to the extent it may be granted at all in cases of disputed fact under the Seventh Amendment, may be granted only "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Bayer has not met its burden to show that no genuine issue exists as to the essential element of causation. As the nonmoving party under Rule 56, Plaintiffs may point to the entire record including "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," to demonstrate the presence of a genuine issue of material fact. *Id.* at 323.

"Summary judgment under Rule 56 of the Federal Rules of Civil Procedure is appropriate only if 'there is no genuine issue as to any material fact and the moving party is entitled to a judgment as a matter of law.'" *Blue Cross & Blue Shield of N.J., Inc. v. Philip Morris, Inc.*, 133 F. Supp. 2d 162, 165 (E.D.N.Y. 2001) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "'In considering the motion, the court's responsibility is not to resolve disputed issues of fact but to assess whether there are factual issues to be tried.'" *Id.* (quoting *Knight v. U.S. Fire Ins. Co.*, 804 F.2d 9, 11 (2d Cir. 1986)). Moreover, "[o]nly when reasonable minds could not differ as to the import of the proffered evidence is summary judgment proper." *Id.*

"If proffered expert testimony is found inadmissible, the district court must make the summary judgment determination on a record that does not include that evidence." *In re Fosamax Prods. Liab. Litig.*, No. 1:06-md-1789 (JFK), 2009 U.S. Dist. LEXIS 82136, at *16 (S.D.N.Y. Sep. 8, 2009). "If, as to the issue on which summary judgment is sought, there is any evidence in the record from any source from which a reasonable inference could be drawn in favor

of the nonmoving party, summary judgment is improper." *Chambers v. TRM Copy Ctrs. Corp.*, 43 F.3d 29, 37 (2d Cir. 1994). Therefore, "[p]ursuant to Fed. R. Civ. P. 56(c), the district court must consider all 'pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits,' in determining whether there is a genuine issue of material fact." *Davis v. New York*, 316 F.3d 93, 100 (2d Cir. 2002). In reviewing all the evidence in the record, the district court "may not make credibility determinations or weigh the evidence. . . . 'Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.'" *Jasco Tools, Inc. v. Dana Corp. (In re Dana Corp.)*, 574 F.3d 129, 152 (2d Cir. 2009) (emphasis in original) (citation omitted). Moreover, "[t]he inferences to be drawn from the underlying affidavits, exhibits, interrogatory answers, and depositions must be viewed in the light most favorable to the party opposing the motion." *Cronin v. Aetna Life Ins. Co.*, 46 F.3d 196, 202 (2d Cir. 1995)*; United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962) (per curiam). The Supreme Court has repeatedly reiterated that "fail[ing] to view the evidence at summary judgment in the light most favorable to [plaintiff] with respect to the central facts of this case," "failing to credit evidence that contradict [the movants' assertions]," and "improperly weigh[ing] the evidence" are reversible error. *Tolan v. Cotton*, 134 S. Ct. 1861, 1866 (2014).

Bayer initially attempts to sidestep this well-settled standard, *see* ECF 329, § I(A), by arguing this Court can ignore the factual record entirely because "[t]he law of every jurisdiction uniformly requires expert testimony to satisfy a plaintiff's burden of proof in cases involving complex issues of medical causation," *id.* at p. 10. Even assuming this proposition is correct and

properly applied to every aspect of causation,[1] this Court has neither requested nor permitted the development of a record that would allow it to determine if *any particular Plaintiff*, much less *all* of the Plaintiffs, could produce admissible expert testimony that could satisfy their burden of proof of establishing causation in their own case through expert testimony. Bayer has not established which parts of causation require expert witness testimony and, even then, Bayer has not established why any particular Plaintiff would be precluded from calling their treating physician or the expert witness of their choice and then using the existing record to establish causation in their case.

Bayer's motion requires this Court make two sweeping holdings: (a) the current record, even weighed in Plaintiffs' favor, nonetheless demonstrates indisputably that levonorgestrel is incapable of causing intracranial hypertension, pseudotumor cerebri, papilledema, and related sequelae; and, (b) no amount of case-specific evidence or expert testimony could convince a trial court otherwise. Such a ruling would be fraught with reversible errors, as would any other path to summary judgment, violating Plaintiffs' procedural rights, basic principles of federalism, or both. Limiting this MDL to the abstract concept of "general causation" has led the litigation into a hole, and there is no way out but vacating the *Daubert* opinion, proceeding to bellwethers, and analyzing those cases individually according to the applicable state substantive tort law.

ARGUMENT

I. THIS COURT HAS IMPROPERLY RELIEVED BAYER OF ITS BURDEN

"A party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings,

[1] For example, it is certainly relevant to causation what symptoms a Plaintiff experienced and whether a Plaintiff's symptoms began after the Mirena was inserted and improved after it was removed, but a Plaintiff would not need expert testimony to establish any of those facts.

depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact.'" *Celotex*, 477 U.S. at 323; *see also Johnson v. Chem. Bank*, 96 Civ. 4262 (SS), 1996 U.S. Dist. LEXIS 18027, at *8 (S.D.N.Y. Dec. 6, 1996) (Sotomayor, J.) (the moving party bears the "initial responsibility … of informing the court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact.") (quoting *Federal Deposit Ins. Corp. v. Giammettei,* 34 F.3d 51, 54 (2d Cir. 1994)).

Here, Bayer demanded and this Court ordered Plaintiffs to produce a list of "admissions" in advance of Bayer's opening brief. ECF 325 (directing Plaintiffs to submit a letter "identifying the alleged admissions as to general causation, made by Bayer or its experts, on which plaintiffs intend to rely in opposing Bayer's motion for summary judgment.") However, Plaintiffs maintain their objection to that procedure in its entirety, as it has no basis in the law, has unduly burdened and unfairly prejudiced Plaintiffs, and turned the summary judgment standard on its head. "[T]he burden of the nonmovant to respond arises only if the motion is properly 'supported' -- and therefore summary judgment only is 'appropriate' when the moving party has met its burden of production under Fed. R. Civ. P. 56(c) 'to show initially the absence of a genuine issue concerning any material fact.'" *Amaker v. Foley*, 274 F.3d 677, 681 (2d Cir. 2001) (quoting *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 159 (1970)). The Second Circuit has instructed: "a court cannot relieve the moving party of its initial burden of production under that rule." *Id.* Thus, requiring Plaintiffs to submit the evidence upon which they intended to rely "in opposing Bayer's

motion for summary judgment" before Bayer had even submitted its motion is contrary to binding precedent in this and every appellate circuit in the United States.

II. EXCLUSION OF "GENERAL CAUSATION" EXPERT TESTIMONY IS NOT PROPER GROUNDS FOR SUMMARY JUDGMENT OF MULTIDISTRICT LITIGATION

A. Defendants Have Not Established That An Abstract Showing Of "General Causation" Is An "Essential Element" Of Any Of Plaintiffs' State Law Claims, Much Less An "Essential Element" Of All Of Them. The Only "Essential Element" Is That Plaintiffs Prove Causation In Their Own Case, With Their Own Evidence.

Bayer has not attempted to establish that "general causation" is an "essential element" to any of the state-law causes of actions raised by any of the Plaintiffs in this MDL, and thus the motion should be denied outright.[2] Although Bayer knew Plaintiffs would raise this issue, see ECF 326, Bayer made little effort to address it. Bayer's Motion on the supposed "essential element" of "general causation" never once defines what "general causation" is, how it could be proven, or why this Court should consider it at all. Instead, Bayer provided a handful of citations in its memorandum and then an "Appendix" consisting solely of string-cites, apparently under the belief it is this Court's job to dig through those cases and create an argument for them. ECF 329, pp. 4-5; ECF 331-1.

All of the cases in this MDL are here by way of diversity jurisdiction. "Under the *Erie* doctrine, federal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Ctr. for Humanities*, 518 U.S. 415, 427 (1996). Of course, the elements of a tort are a

[2] Even the Restatement (Third) of Torts, which is generally perceived as more defendant-friendly than the Second Restatement, holds that "'exposure,' 'general causation,' and 'specific causation' … are not 'elements' of a plaintiff's cause of action." Restatement (Third) of Torts: Liability for Physical and Emotional Harm § 28 cmt. c, at 405 (2010).

matter of state law, not federal law — there is no federal rule that even attempts to displace the elements of state tort law. *See, e.g.*, *Shady Grove Orthopedic Associates v. Allstate Ins.*, 559 U.S. 393, 409 (2010)("In sum, it is not the substantive or procedural nature or purpose of the affected state law that matters, but the substantive or procedural nature of the Federal Rule.") MDL courts have never held otherwise. *See, e.g.*, *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 802 (N.D. Ohio 2004); *accord In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, No. MDL No 2:14-mn-02502-RMG, 2016 U.S. Dist. LEXIS 186282, at *21-24 (D.S.C. Dec. 29, 2016).

Bayer's Motion, therefore, depends first and foremost on Bayer establishing that *state* law deems an abstract showing of "general causation" an "essential element" of the claims of each and every Plaintiff in this MDL. Bayer, however, does not attempt to do so, much less persuasively establish that the laws of all fifty states permit this Court to eliminate the ordinary elements of Plaintiffs' claims and replace them all with an undefined federal "general causation" standard in lieu of each Plaintiff proving causation in their own case according to applicable state law. Instead, Bayer provides a handful of federal court opinions with scattered language that includes the phrase "general causation," as if a federal court could modify substantive state law by citing other federal courts. None of these cases hold that federal law creates a generic element of "general causation" that supplants state tort law, nor could they. Similarly, none of the cases hold this Court can abandon the tried-and-true principle of tort law that a plaintiff is entitled to present evidence the defendants caused their particular injury.

Second Circuit law governs the interpretations of federal law even when the case is transferred from a court sitting in another circuit, and so it governs interpretations of federal law

in these cases.[3] The only two Second Circuit cases cited by Bayer, *Mirena I* and *Amorgianos*, offers Bayer no help in this regard. The plaintiffs in *Mirena I* conceded this issue for the convenience of moving forward more quickly. In *Amorgianos*, 303 F. 3d 256, 268 (2d Cir., 2002), the Second Circuit does not state that a plaintiff must first generically prove "general causation" before being permitted to introduce evidence on general causation, and the opinion cites just two cases related to "general causation," the District Court's opinion in *Amorgianos* and *Zuchowicz v. United States*, neither of which supports Bayer's position. In *Amorgianos*, the District Court based its "general causation" holdings on *Mancuso v. Consolidated Edison Co. of N.Y.*, 56 F.Supp.2d 391 (S.D.N.Y.1999), which in turn referenced "general causation" on the basis of two non-legal sources, the World Health Organization and the National Academy of Science, neither of which has the power to alter the substantive tort law of all fifty states. *See id.* at 394-95.

In *Zuchowicz*, the Second Circuit recognized, just as Plaintiffs argue here, that *state* law determines what must be proven to establish the element of causation: "[i]n seeking to show both components of but for causation, plaintiff's reliance on experts must meet the substantive requirements *of Connecticut law*." 140 F. 3d 381, 389 (2d Cir., 1998)(emphasis added). The Court in *Zuchowicz* then reviewed Connecticut state law, never once mentioned any requirement of "general causation," and instead *rejected* the defendants' arguments against causation, finding that a doctor's "long experience" with the condition suffered by the plaintiff and his opinion there was a causal link between the plaintiff's exposure and the disease was more than sufficient to establish causation. *Id.* at 391. Applying the *Zuchowicz* standard here would require denying Defendants'

[3] *Liberty Synergistics Inc. v. Microflo Ltd.*, 718 F.3d 138, 154 n.17 (2d Cir. 2013); *accord Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 90 (2d Cir. 2006) ("As to issues of federal law, we are permitted — indeed, required — to reach our own conclusions.").

motion in its entirety, vacating the prior *Daubert* order, and selecting bellwethers to proceed to trial.

In *Wells v. SmithKline*, a single plaintiff disclosed three experts who themselves denied a causal relationship between the drug (Requip) and his injury (compulsive gambling). 601 F.3d 375, 379 (5th Cir., 2010). As the Fifth Circuit recognized, "these admissions drain the expert opinions of probative force," and summary judgment was affirmed. The plaintiff in *Wells* was neither required to produce expert testimony restricted to general causation in the abstract, like in this case, nor prohibited from producing expert testimony on specific causation, like in this case. Rather, the plaintiff failed to provide evidence of either.

The plaintiff in *Norris v. Baxter* was similarly not constrained like the Plaintiffs here, and the plaintiff at issue in fact produced *specific causation* expert testimony in the form of differential diagnoses. There, the Tenth Circuit held the plaintiff's experts' "reliance on differential diagnosis without supporting epidemiological evidence is misplaced and demonstrates the unreliable nature of the testimony." 397 F. 3d 878, 885 (10th Cir. 2005). Plaintiffs have previously briefed how *Daubert* does not require epidemiological evidence and how the epidemiological evidence in this case supports causation and they do so again below; for purposes here, the relevant point is that *Norris*, too, did not hold that federal courts could replace the elements of state law, which require only that a plaintiff prove causation in their own case. Bayer's string-cite of other cases fare similarly. For example, *In re Lipitor* holds, as Plaintiffs argue here, "state substantive law governs the means by which each plaintiff must prove her specific tort case," 892 F.3d 624 (4th Cir., 2018), then never attempts to ground in state law any requirement plaintiff succeed at proving "general causation" in the abstract before being allowed to prove causation in their own case.

The Rules of Civil Procedure and the Rules of Evidence do not empower federal courts to modify the elements of state tort law — elements which ask a plaintiff to prove causation in their own case, not causation in an abstract sense divorced from their own evidence — no matter how convenient in may be to do so. Congress specifically limited those Rules so that they "shall not abridge, enlarge or modify any substantive right," 28 U.S.C. § 2072, and the Supreme Court has "long held" that this means the "Rules must really regulate procedure," such that any use of the Rules which "alters the rules of decision by which the court will adjudicate those rights" is invalid. *Shady Grove*, at 406 (internal quotations omitted). Defendants have not identified a single instance from *any* state, much less persuasive examples across *all* states, in which a Plaintiff was required, as an "essential element" of their tort claims, to establish "general causation" in the abstract before being permitted to introduce evidence of causation in their particular case.

Bayer claims to have an answer to this, its "Appendix: 53-Jurisdiction Survey of the Laws on Causation in Product Liability Actions," which cites hundreds of cases with no explanation whatsoever. Even a brief glance reveals problems. For example, the first case listed in Pennsylvania is *Hamil v. Bashline*, 392 A.2d 1280 (Pa. 1978), a *medical malpractice* case, not a product liability case, which laid down a rule for causation that is decidedly unhelpful for Bayer:

> Whether in a particular case that standard has been met with respect to the element of causation is normally a question of fact for the jury; the question is to be removed from the jury's consideration only where it is clear that reasonable minds could not differ on the issue. In establishing a *prima facie* case, the plaintiff need not exclude every possible explanation of the accident; it is enough that reasonable minds are able to conclude that the preponderance of the evidence shows defendant's conduct to have been a substantial cause of the harm to plaintiff.

Id. (citations omitted). The substantive law of causation in Pennsylvania thus directly contradicts this Court's *Daubert* order, which faulted Plaintiffs' experts for failing to exclude alternative causes. *See, e.g.*, ECF 320, p. 57. Indeed, *Hamil* is beloved by the plaintiffs' bar of Pennsylvania

precisely because of the causation standard it outlines, permitting a plaintiff to prevail whenever they have demonstrated the defendants' conduct "increased the risk of harm to another," which "furnishes a basis for the fact-finder to go further and find that such increased risk was in turn a substantial factor in bringing about the resultant harm; the necessary proximate cause will have been made out if the jury sees fit to find cause in fact." *Id.* At no point did this Court's *Daubert* opinion examine "general causation" under the framework of whether there was reliable expert testimony that Mirena could "increase the risk" of intracranial hypertension.

Indeed, the majority of citations in Bayer's "Appendix" are not actually citations to the state courts which determine the content of substantive state tort law, but rather citations to federal courts which lack the power to "abridge, enlarge or modify any substantive right," 28 U.S.C. § 2072. Digging deeper into Bayer's "Appendix: 53-Jurisdiction Survey of the Laws on Causation in Product Liability Actions," the citations appear downright deceptive. For Illinois, Bayer cites a single 1996 opinion from an intermediate appellate court in Illinois, then cites only federal cases. Perhaps Bayer did so because the Illinois Supreme Court subsequently rejected Bayer's claim that their undefined version of "general causation" is an essential element to tort claims in all fifty states:

> Illinois law does not define causation in terms of "generic" or "specific" causation. Rather, our case law clearly states that in negligence actions, the plaintiff must present evidence of proximate causation, which includes both "cause in fact" and "legal cause." A plaintiff may show "cause in fact" under the substantial factor test, showing that the defendant's conduct was a material element and substantial factor in bringing about the alleged injury. . . .

Donaldson v. Central Illinois Public Service Company, 199 Ill. 2d 63 (2002), *abrogated in part on other grounds by People v. Simons (In re Simons)*, 213 Ill. 2d 523 (2004) (internal citations omitted).

Bayer's review of Kansas law, citing seven cases with no explanation, similarly somehow missed the Kansas Supreme Court bluntly declaring "[n]o Kansas cases have required a finding of general causation in order to admit evidence pertaining to specific causation under the *Frye* test." *Kuhn v. Sandoz Pharmaceuticals Corp.*, 270 Kan. 443, 464 (2000). Bayer's review of Texas law left off the Texas Supreme Court explicitly holding that a Plaintiff can skip *both* general *and* specific causation if they have evidence of an increased risk, like the Plaintiffs have in this MDL:

> In the absence of direct, scientifically reliable proof of causation, claimants may attempt to demonstrate that exposure to the substance at issue increases the risk of their particular injury. The finder of fact is asked to infer that because the risk is demonstrably greater in the general population due to exposure to the substance, the claimant's injury was more likely than not caused by that substance. Such a theory concedes that science cannot tell us what caused a particular plaintiff's injury. It is based on a policy determination that when the incidence of a disease or injury is sufficiently elevated due to exposure to a substance, someone who was exposed to that substance and exhibits the disease or injury can raise a fact question on causation.

Merrell Dow Pharmaceuticals, Inc. v. Havner, 953 SW 2d 706, 715 (Tex 1997). As shown below, Plaintiffs have not just evidence that "exposure to the substance at issue increases the risk of their particular injury" in the form of years of peer-reviewed literature and recent medical guidelines, but also evidence particular to LNG-releasing intrauterine implants in the form of peer-review literature (Valenzuela), Bayer's own disproportionality database (Empirica), and testimony from Bayer's own paid expert epidemiologist (Dr. Langer).

Even the states that recognize "general causation" do not hold that a plaintiff must prove "general causation" in the abstract before being allowed to submit evidence of specific causation. Moreover, those states constrain the concept of "general causation" with a multitude of caveats. New York, for example, specifically held "it is not always necessary for a plaintiff to quantify exposure levels precisely or use the dose-response relationship, provided that whatever methods

an expert uses to establish causation are generally accepted in the scientific community." *Parker v. Mobil Oil Corp.*, 857 NE 2d 1114 (N.Y. 2006). Thus, in a case tried under New York law, this Court's *Daubert* opinion, which relied heavily on dose-response relationships and which faulted Plaintiffs' experts for inadequately demonstrating them,[4] would be of no use at all in determining whether the plaintiff had evidence sufficient to establish general causation.

The bar for establishing "general causation" in states that recognize the concept is exceeding low, far lower than the standard used by this Court's *Daubert* opinion. That bar can be met, for example, by a medical doctor who reviewed no literature and never examined the patients. *Terry v. Caputo*, 115 Ohio St. 3d 351, 353, 358 (2007) (holding doctor's "testimony was reliable and relevant on the issue of general causation," even where his differential diagnosis was "invalid" and "unreliable" for specific causation). Bayer's "Appendix" cites *Ranes v. Adams Laboratories, Inc.*, from Iowa, but that case made the bar for general causation as low as it could conceivably be: "the plaintiff's expert must only be qualified to offer a theory of causation for the jury's consideration, not absolute certainty." 778 NW 2d 677, 688 (Iowa 2010). Iowa is thus another state where the Court's advisory *Daubert* opinion cannot be used to decide whether any Iowa Plaintiffs have sufficient evidence of general causation under Iowa law. These problems are entirely of Bayer's own making by urging the Court to rule on evidentiary matters unmoored from any applicable state substantive law and then moving for summary judgment on an "essential element" that many states do not recognize at all and which no state recognizes in the manner

[4] See, e.g., ECF 320, p. 49, Fn 30: "However, on the record before the Court, those materials do not indicate, with respect to short-term exposure to LNG, a dose-response relationship with respect to IIH." The Court's factual conclusion was inappropriate and erroneous for *Daubert*; for purposes here, the additional problem is that this Court's conclusion about a dose-response relationship is inconsistent with New York substantive law.

suggested by Bayer. The cart (federal evidentiary rulings) was put before 53 horses (the substantive law of the states plus Puerto Rico, Virgin Islands, and the District of Columbia), making it impossible for any of them to pull it. An ordinary bellwether process of particular Plaintiffs with particular substantive law would not have any of these problems, and the solution is to vacate the *Daubert* order and utilize a normal bellwether process.

The above is far more exhaustive an analysis of state law than Bayer attempted provide, even though Bayer is the movant and thus the party obliged to spell out the law it asks this Court to apply. Moreover, no matter how many new deceptive citations Bayer provides in its reply, these cannot serve as a substitute for the "deep-rooted historic tradition that everyone should have his own day in court." *Taylor v. Sturgell*, 553 U.S. 880, 892-93 (2008) (quoting *Richards v. Jefferson Cty.*, 517 U.S. 793, 798 (1996)).[5] Even a bellwether is not sufficient to bind other Plaintiffs.[6] Here, the Court has not permitted, much less considered, the full evidence that *any* Plaintiff would bring to their own day in court to prove their state law tort claims. Instead, the court has, with its *Daubert* order on the non-existent element of "general causation" with no facts particular to any Plaintiff, entered an impermissible "opinion advising what the law would be upon a hypothetical state of facts." *MedImmune, Inc. v. Genentech, Inc.*, 549 US 118, 127 (2007) (quotation omitted). A federal court dismissing hundreds of individual Plaintiffs' State-law claims based on an amorphous

[5] To the extent Bayer attempts to do so, Plaintiffs renew their request for leave to file a sur-reply to address any new arguments raised in Bayer's reply. *See* ECF 324.

[6] *See, e.g.,* Eldon E. Fallon et al., Bellwether Trials in Multidistrict Litigation, 82 Tul. L. Rev. 2323, 2332 (2008)(bellwether trials are not a "representative proceeding"). *See also* Martin H. Redish & Julie M. Karaba, One Size Doesn't Fit All: Multidistrict Litigation, Due Process, and the Dangers of Procedural Collectivism, 95 B.U. L. Rev. 109, 126 (2015) (bellwether trials "are not binding on other parties in the MDL").

inessential matter none of them are obliged to prove under State law would be blatantly unconstitutional, violating the case-or-controversy requirement and the Seventh Amendment.[7]

B. The Court's Restriction Of This Case To "General Causation" Has Denied Plaintiffs Their Right To Obtain And To Proffer Case-Specific Evidence, Including Expert Witness Testimony On Causation, Such As A Differential Diagnosis.

Under the schedule ordered by this Court, over Plaintiffs' objection, "general causation" was separated from "case-specific" discovery, and so none of the existing record addresses what evidence of causation Plaintiffs would proffer in their individual cases. The record is thus inherently insufficient for summary judgment, which Bayer admits is both the primary method for determining if a patient has PTC *and* is the primary method for determining the cause of PTC. ECF 326, #29, #30. One glaring example is the absence of differential diagnoses. Many Plaintiffs have had their own doctors determine, through differential diagnosis, that the Mirena was the cause of their intracranial hypertension, and other Plaintiffs could obtain expert witness testimony of the same. Yet, this Court has not permitted evidence of either to enter the record. In the real world, no doctor or scientist would attempt to determine the cause of a patient's intracranial hypertension without a differential diagnosis, and yet this Court has not permitted any Plaintiffs to do the same, and Bayer now asks the Court to forego that entirely.

As one MDL court noted, "[t]he Court of Appeals for the Third Circuit concluded that there is no federal rule requiring expert testimony in support of general causation in mass tort claims." *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 802 (N.D. Ohio 2004) (citing *In re*

[7] Furthermore, to the extent Plaintiffs have not waived their rights under *Lexecon Inc. v. Milberg Weiss*, 523 U.S. 26 (1998) (ECF 35, CMO 3), entering summary judgment against them before they have had the opportunity to present the evidence they would present at trial amounts to a violation of *Lexecon*.

Paoli R.R. Yard PCB Litig., 35 F.3d 717, 750-52 (3d Cir. 1994)). "The court noted that such a rule would be, in part, (1) a rule regarding what types of evidence are admissible in mass tort cases, and (2) an aspect of a party's burden of proof." *Id.* As to the first prong, the Second Circuit has indicated that a differential diagnosis may provide a sufficient basis for a causation opinion: "There may be instances where, because of the rigor of differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance, a differential diagnosis is sufficient to support an expert's opinion in support of both general and specific causation." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005); *see also, e.g., C.W. v. Textron, Inc.*, 807 F.3d 827, 839 (7th Cir. 2015) (recognizing "[t]he Second Circuit already takes this approach."). Indeed, in *McCullock v. H.B. Fuller Co.*, the Second Circuit affirmed the admissibility of a causation opinion based on differential etiology including care and treatment of plaintiff, medical history, pathological studies, product's safety data sheet, reference to scientific and medical treatises, the expert's training and experience. 61 F.3d 1038 (2d Cir. 1995). Thus, "[t]he district judge has broad discretion in determining whether in a given case a differential diagnosis is enough by itself to support such an opinion." *Ruggiero*, at 254. Exercising this broad discretion, several district courts in the Second Circuit have admitted expert causation testimony based on differential diagnosis methodology. *See Perkins v. Origin Medsystems, Inc.,* 299 F. Supp. 2d 45, 57 (D. Conn. 2004) ("Differential diagnosis is a reliable basis to prove general causation in this circuit."); *Roman v. Sprint Nextel Corp.*, No. 12-CV-276 (VEC), 2014 U.S. Dist. LEXIS 138951, at *30-31 (S.D.N.Y. Sep. 29, 2014) ("A differential diagnosis may provide a reliable foundation for an expert's opinion on general causation"); *c.f.*, *Danley v. Bayer (In re Mirena IUD*

Prods. Liab. Litig.), 169 F. Supp. 3d 396, 454 n.55 (S.D.N.Y. 2016) (noting that differential etiology "can be a sufficiently reliable methodology to opine on causation.")

There is nothing unusual about using a differential diagnosis to establish causation. Other Circuits, even while finding particular instances unreliable or admissible, have ensured to note that a differential diagnosis can be an appropriate method of establishing causation. See, e.g., *Westberry v. Gislaved Gummi AB*, 178 F. 3d 257, 263 (4th Cir. 1999)(collecting cases, holding "a reliable differential diagnosis provides a valid foundation for an expert opinion."); *accord Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010)(recognizing the same, and noting "a reliable differential diagnosis need not rule out all possible alternative causes").

In fact, numerous plaintiffs in this MDL already have admissible medical records indicating causation via differential diagnosis, and these records must be considered in each Plaintiff's case. Yet, because of this Court's bifurcation of discovery, none of these records are part of the MDL record, none of Plaintiffs' treating providers have been deposed, and no Plaintiff has submitted expert testimony regarding their diagnosis or the cause thereof. One such example includes:

> We discussed that Mirena is likely contributing and if we do not find alternative cause on MRI today, the Mirena IUD should be removed and she should discuss alternative birth control with her OBGYN rapidly as pregnancy can worsen the condition. She should go on birth control not associated with IIH.

Ex. 1A, Redacted Record (Plaintiff C. Reid); See also Ex. 1B, Redacted Record (Plaintiff B. Pieters) ("Disc edema, OU most likely due to pseudotumor cerebri induced by Mirena intrauterine contraceptive agent."); Ex. 1C, Redacted Record (Plaintiff E. Silva) ("recommend remove her Mirena IUD, which contains levonorgestrel, and there have been case series reporting an association between this hormone and pseudotumor cerebri."); Ex. 1D, Redacted Record (Plaintiff K. Cheek) ("only risk is Mirena (IUD with levonorgestrel) - which she is having removed today

[…]"); Ex. 1E, Redacted Record (Plaintiff N. Johnson) ("She is followed [ ] at [] Neurology who believes her condition may be a result of the Mirena").[8]

III. PARTY ADMISSIONS ARE APPROPRIATELY CONSIDERED IN OPPOSITION TO SUMMARY JUDGMENT

The nonmoving party under Rule 56 may point to the entire record including "the pleadings, depositions, answers to interrogatories, and *admissions* on file, together with the affidavits, if any," to demonstrate the presence of a genuine issue of material fact. *Celotex*, 477 U.S. at 323 (emphasis added and internal quotations omitted). And, "because admissions against a party's interests are received into evidence without many of the technical prerequisites of other evidentiary rules — such as, for example, trustworthiness and personal knowledge — admissibility under the rule should be granted freely." *Pappas v. Middle Earth Condo. Ass'n*, 963 F.2d 534, 537 (2d Cir. 1992). Thus, party admissions are appropriately considered in opposition to summary judgment.

The Second Circuit has not held, as Bayer suggests, that admissions *cannot* "replace expert testimony." ECF 330 at p. 8. Although Judge Seibel declined to accept the plaintiffs' proffered admissions in place of expert testimony, the Second Circuit indicated that admissions rising to a certain level *could* establish general causation. *See Mirena MDL v. Bayer Healthcare Pharm. Inc. (In re Mirena IUD Prods. Liab. Litig.)*, 713 F. App'x 11, 15-16 (2d Cir. 2017) (declining to hold that admissions could never substitute for expert testimony, but finding that the purported admissions

[8] Attached hereto as collective Ex. 1. These examples are merely illustrative and are not exhaustive of Plaintiffs in this MDL and potential plaintiffs throughout the country with such evidence in their medical records. Furthermore, even Plaintiffs whose records do not explicitly mention Mirena or causation are entitled to depose their treating providers and to present their own expert witnesses that have reviewed their medical history and records related to Mirena and IH.

there were not enough); *see also Lipitor*, 892 F.3d at 647 (finding the plaintiffs' proffered "present[ed] a closer question than in *Mirena*[.]"); *In re Benicar (Olmesartan) Prods. Liab. Litig.*, 2016 U.S. Dist. LEXIS 156182, at *163 (D.N.J. Nov. 8, 2016) (where information proffered as "admissions" in opposition to summary judgment "is clear, unambiguous, and concrete and suffices to prove general causation without the jury's speculation as to complex medical issues" it may "substitute for *Daubert*-admissible expert testimony of general causation.")

Bayer's Motion frames the issues here as if the only probative admissions would be "company endorsements of causation" or a "concession of causation" by Bayer that Mirena causes intracranial hypertension. ECF 329, pp. 9-10. That is nonsense.[9] Evidence less than a full confession can be probative of a disputed issue, as recognized by *Mirena I*, *Lipitor*, and *Benicar*, *supra*. To impose a requirement the defendant make an "endorsement" or "concession" of causation would make it impossible to support causation using admissions — which is exactly what the Second and Fourth Circuits refused to do. Searching the record solely for "endorsements" or "concessions" of a disputed element would violate basic principles of summary judgment, in which the court views the record as a whole in the light most favorable of the non-movant. Moreover, the actual *triable issue of causation* is not the abstract issue of "general causation," but rather if a particular Plaintiffs' injuries were caused by Mirena.

Rather, the question is if the admissions, viewed together as a whole, are sufficient to create a triable issue of fact on causation. Further, in the present posture of this case, in which no Plaintiffs have undergone discovery with regard to specific causation (which is the actual element they must

[9] If a defendant admitted throwing an axe at a plaintiff but disputed causing their injury, the admission about the thrown axe would still be relevant and admissible towards proving causation.

prove at trial), the question is if the admissions could be sufficient, when paired with a case-specific expert witness, to create a triable issue of fact on causation in any of the Plaintiffs' cases.

Here, the evidence supporting causation includes peer-reviewed, published scientific literature that has only ever been criticized by Bayer's lawyers and paid experts; formal admissions by Bayer; testimony of Bayer's corporate representatives[10] and paid experts; and undisputed portions of Plaintiffs' expert testimony. This admissible evidence on causation must be heard by a jury.

IV. THE RECORD REFLECTS A GENUINE ISSUE OF MATERIAL FACT AS TO CAUSATION SUPPORTED BY ADMISSIBLE EVIDENCE

Weighing the evidence in Plaintiffs' favor at summary judgment, the Court must begin its analysis with a simple medical and scientific fact: "there is a well established relationship between PTC and levonorgestrel-releasing implants. Headache is a common adverse effect of levonorgestrel; patients developing headaches or visual disturbances while using it should be

[10] Numerous district courts have treated testimony of corporate representatives as party admissions. *See, e.g., Newcom Holdings Pty. Ltd. v. Imbros Corp.*, 369 F. Supp. 2d 700, 709 n.12 (E.D. Va. 2005) ("Benson is plaintiff's corporate representative and, therefore, his statement to Colton constitutes a party admission."); *HTI Holdings,* 2011 U.S. Dist. LEXIS 94388, at *15 ("Similarly, Hartford's objection to HTI's use of Pawloski's testimony is not persuasive—as Hartford's 30(b)(6) witness, Pawloski's testimony is both admissible and binding."); *Caicedo v. Food for Life Experience, Inc.*, No. 1:13-cv-00258-GRJ, 2014 U.S. Dist. LEXIS 90312, at *8 (N.D. Fla. July 2, 2014) ("As the 30(b)(6) representative the testimony of the witness is binding on the corporation and serves as a party admission."); *see also Ecoservices, LLC v. Certified Aviation Servs., LLC*, 312 F. Supp. 3d 830, 839 (C.D. Cal. 2018) (corporate witness's statements admissible under the party admission exception to hearsay) (quoting Fed. R. Civ. P. 32(a)(3) ("an adverse party may use for any purpose the deposition of a party or anyone who, when deposed, was the party's . . . designee under Rule 30(b)(6).")).

evaluated for funduscopic evidence of PTC."[11] Just last month, the European Headache Federation's Guideline on Idiopathic Intracranial Hypertension noted "oral contraceptives" and "levonorgestrel implant system" are medications "that may induce a secondary elevation of [intracranial pressure] or produce symptoms that may mimic IIH."[12]

If "general causation" is defined as "whether a substance is capable of causing or exacerbating a particular harm" — a definition Plaintiffs had to create themselves from scratch for the Court-ordered admissions letter, ECF 326, because Bayer never defined "general causation" and even in its Motion *still* refuses to provide any explanation of this supposed "essential element" of Plaintiffs' claims — then every Plaintiff in this MDL can walk into Court with peer-reviewed literature from experts, guidelines from medical associations, and FDA determinations which establish exactly that: the levonorgestrel in Mirena is capable of causing headaches, visual disturbances, pseudotumor cerebri, secondary elevation of intracranial pressure, and intracranial hypertension.[13] Plaintiffs and their experts would further be using the wealth of admissions made by Bayer and its experts to buttress their opinions. If this Court had permitted case-specific discovery, then many Plaintiffs would be doing exactly that, with experts or treating physicians

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[11] *See, e.g.*, ECF 174, p. 13. Friedman DI. Medication-induced intracranial hypertension in dermatology. Am J Clin Dermatol 2005;6:29–37. This article remains a standard text in the field, and it is cited by several of the studies Defendants' experts rely on, such as Daniels 2007.

[12] Hoffmann, J., Mollan, S.P., Paemeleire, K. et al. J Headache Pain (2018) 19:93. https://doi.org/10.1186/s10194-018-0919-2.

[13] The writings and testimony of Bayer's own experts would also be available for Plaintiffs. Bayer's neuro-ophthalmology expert, Dr. Newman admits, in the published scientific literature, "levonorgestrel" is among the "various medications [that] have been proposed to cause or precipitate [IIH]," and that "it is appropriate to discontinue potentially associated medications." ECF 166-2 (Newman Dep. at 98:1-99:17). For purposes of summary judgment, Dr. Newman's writing and testimony can *only* be interpreted as admitting "general causation." It would not be "appropriate to discontinue" a medication incapable of causing intracranial hypertension, it would be malpractice.

reviewing their medical records, the relevant literature, and then opining, such as through a differential diagnosis, that the Plaintiff's Mirena had caused the Plaintiff's injuries. As explained below, however, the foregoing is not the only evidence of causation available to Plaintiffs, even without any "general causation" experts.

A. Plaintiffs' General Causation Experts Still Have Admissible Testimony Relevant To Causation

The proper role of the expert witness is not to offer pure conclusions of law, but to aid the fact finder. "Generally, expert testimony may be admissible if it is helpful to the trier of fact." *United States v. Duncan*, 42 F.3d 97, 101 (2d Cir. 1994) (citing Fed. R. Evid. 702). This Court has acknowledged Bayer's failure to contest or refute a number of opinions and facts and data in support thereof proffered by Plaintiffs' experts, and these facts and opinions must reach a jury. Therefore, although this Court has rejected Plaintiffs' experts' ultimate conclusions, it is undisputed that Plaintiffs' experts have offered admissible testimony that will aid a jury in determining the issue of causation.

Plaintiffs are not required to offer a single expert capable of explaining both the pertinent properties of levonorgestrel ("LNG") *and* the pathophysiologic processes by which it may cause PTC/IH, no such requirement exists. Even Bayer did not dispute this general proposition at the *Daubert* hearing in this matter:

> THE COURT: Suppose there was evidence elsewhere in the record. [Salpietro] just didn't have it. In other words, that his model, such as it is, stopping short of LNG, was properly received and there was other evidence in the record that supported the proposition that LNG was an agonist. What then? In other words, can general causation be established by stitching together building blocks from different sources? They are not all endemic to this one expert.
>
> MR. EVANS: I think that's an interesting question, your honor. I think that in some abstract theory you could have someone come in and say, I am going to take this piece of the equation this far, and then you can have another expert say, I am going to take this from there to the goal line. I get that and I am not disagreeing with

that.

Tr. of 04/11/2018 *Daubert* Hearing at 273:9-273:22. This understanding is consistent with the requirement that an expert's "testimony 'advance[s] a material aspect' of the plaintiffs' product liability case," and a plaintiff may designate multiple experts, each "to establish one piece of the larger specific causation puzzle." *Ferguson v. Riverside Sch. Dist. No. 416*, No. CS-00-0097-FVS, 2002 U.S. Dist. LEXIS 28851, at *10-11 (E.D. Wash. Feb. 5, 2002) (quoting *Schudel v. GE*, 120 F.3d 991, 996 (9th Cir. 1997)). Here, Plaintiffs have enlisted some of the world's most qualified experts in the fields most pertinent to both the drug and disease at issue in this litigation, and are entitled to advance the causation element of their case by established pieces of the larger causation puzzle through their "unusually well qualified" experts. *See* Tr. of 04/11/2018 *Daubert* Hearing at 243:20-243:24 (Bayer agreeing with the Court's assessment of Dr. Johanson as "unusually qualified in the area of discussing, let's say cerebrospinal fluid dynamics."); *see also* ECF 199-17 (Hewitt Dep.), at 24:25-25:22 (Bayer's expert gynecologist recognizing that Dr. Darney is "highly respected in the field around contraception and family planning. I think historically he's been a thought leader in the field of contraception and family planning. […] I would say that Phil Darney's reputation is that he is known for being very active and one of the initial sort of founders of the world of contraception and family planning.").

Plaintiffs have put forth admissible expert testimony on the pharmacology and pharmacokinetics of LNG. Bayer has conceded, as the Court has acknowledged, the entirety of Dr. Plunkett's pharmacology and pharmacokinetics opinions. ECF 320, p. 65 ("Bayer either concedes or does not substantially contest most of this discussion.") Likewise, Bayer has conceded the majority of Dr. Darney's pharmacology and pharmacokinetics opinions. *See, e.g.*, ECF 320, p.

111 ("The Court recaps Dr. Darney's proposed testimony as to each of these propositions. The instant *Daubert* litigation focuses on the fourth of these propositions."); ECF 199, p. 18 ("Bayer Does Not Seek Exclusion of Three of Four of Dr. Darney's Opinions Offered in His Expert Report"). Additionally, Plaintiffs have put forth admissible expert testimony regarding the pathological processes involved in cerebrospinal fluid regulation and the interactions of hormones in the relevant regions of the brain. For example, Bayer "did not oppose Dr. Johanson's description of the blood-brain barrier or the blood-CSF barrier. Nor did [Bayer] argue that it is impossible for LNG to cross the blood-brain barrier or the blood-CSF barrier. [Bayer] did not even contest Dr. Johanson's statement that LNG can reach the choroid plexus region." ECF 225, at p. 5. Finally, Plaintiffs are entitled to seek testimony from the non-disclosed experts from whom this Court sought background knowledge on these and related matters on Science Day. *See* ECF 250, 03/30/2018 Order (enumerating the topics to be discussed at Science Day). Unquestionably, Plaintiffs in this MDL may establish "piece[s] of the larger specific causation puzzle" through this testimony. *Ferguson*, at *10-11.

B. Bayer's Expert Witness Testimony Includes Admissible Evidence Of Causation

Bayer claims in its Motion that Plaintiffs' proffered admissions are "[d]etached from any sponsoring expert" ECF 330, p. 3.[14] First, this is not so: the Court has not permitted case-specific discovery, so it has no basis on which to rule that any particular Plaintiff, much less all of them, would not have a "sponsor expert" for some or all of the material facts outlined in this section. Second, this Court has "denie[d] as potentially moot plaintiffs' *Daubert* motions aimed at Bayer's

[14] As noted several times herein and in Plaintiffs' letter (ECF 326), in opposition to summary judgment Plaintiffs are not limited to the "admissions" listed in their letter and maintain their objection to the Court's "Admissions" Order (ECF 325) in its entirety.

general-causation experts," ECF 320 at p. 2, but the testimony of Bayer's proffered experts is far from moot, and must either be admitted or excluded prior to the entry of judgment because this Court has considered it in reaching its *Daubert* decision, and because it is indisputably part of the record in this litigation:

> MR. SCHMIDT: I think the point I was trying to make, I don't think there is anything wrong with your Honor looking to our experts in addressing their motions. I want to be clear on something that I think your Honor was pressing on that I wasn't clear on and that Ms. Cook addressed at the last hearing, which is, we do hold the position. We did write our briefs so that our challenges to their expert stands stand on their own, and our view is your Honor doesn't need to look to our experts in addressing that. I just wanted to clarify that.
>
> THE COURT: That's where I was going because I read your briefs directed at the plaintiffs' experts to notably not quote the defense experts. So whatever mileage one could or couldn't get out of the defense expert's reports, **to the extent they are critiques of the plaintiffs' expert methodology as opposed to substantive commentary on whether there is or there isn't proof of general causation out in the world**, I understood you to be saying, we are not asking you to rely on our experts in ruling on the Daubert as it relates to the plaintiffs.
>
> Do I read that right?
>
> MR. SCHMIDT: Yes, that's correct. That's why I wanted to come back to your Honor.
>
> * * * * *
>
> MR. KENNERLY: Your Honor, if I may, I'm a little confused if defendants' experts in their experts are part of the record or not because Mr. Schmidt was talking about how your Honor may look to them and, at least as I understand it, it's in the record or it's not in the record.
>
> THE COURT: **It's in the record.** The reason I engaged in the colloquy with Mr. Schmidt yesterday was precisely for the reason that I just said with him, and that I think is implicit in what you are saying, which is this.
>
> There has been a lot of litigation here, to say the least. I want to make sure that counsel have a full and fair opportunity to meet the other side's arguments.
>
> * * * * *
>
> THE COURT: Yes. **It's part of the record. It's not unreasonable for me to look at it.**

Tr. of 04/11/2018 *Daubert* Hearing at 239:17-240:12; 241:14-241:24; 242:10-242:11 (emphasis added). Therefore, in considering the entire record before it, this Court must consider the

testimony of Bayer's proffered experts, and must resolve all ambiguities therein in Plaintiffs' favor. *See HTI Holdings, Inc. v. Hartford Cas. Ins. Co.*, No. 10-cv-06021-TC, 2011 U.S. Dist. LEXIS 94388, at *15 (D. Or. Aug. 23, 2011) (testimony of nonmoving party's own expert admissible as a party admission under FRE 801(d)(2)); *Dean v. Watson*, 1995 U.S. Dist. LEXIS 17333, No. 93 C 1846, at *10 (N.D. Ill. Nov. 16, 1995) (permitting use of opposing party's expert's deposition testimony at trial as a party admission); *see also, Envtl. Conservation Org. v. Bagwell*, No. 4:03-CV-807-Y, 2005 U.S. Dist. LEXIS 21669, at *2 n.1 (N.D. Tex. Sep. 28, 2005).

Even if this Court erroneously concludes "general causation" is an essential element of Plaintiffs' claims, and even if Plaintiffs are erroneously precluded from calling case-specific causation experts to offer opinions consistent with the substantive law of their respective states, Bayer's experts provide extensive admissible expert testimony on the methodology that a jury would use to assess "general causation:" Bradford-Hill. Bayer's experts elaborated how, for example, "the framework does not provide a threshold for causal inference based on meeting some number of the criteria, and no single criterion is sufficient to determine an association is causal. Rather, the more criteria that are met or not met, provides more insight into the likelihood the observed association may or may not be causal." ECF 176-1, p. 5 (Report of Dr. Lee); see also ECF 173-1, p. 58 (Report of Dr. Barnhart)("the Hill criteria are not designed to be applied as an 'all or nothing' exercise: a finding that there is no causation does not require that none of the criteria are met, and a finding that there may be causation does not require that every one of the nine criteria are met.") Just through Bayer's experts, whose testimony cannot be ignored at summary judgment, a jury will have all they need to evaluate "general causation." A jury does not need an

expert explicitly telling there is "general causation," and such testimony would be inadmissible anyway:

> [E]xpert testimony that usurps either the role of the trial judge in instructing the jury as to the applicable law, or the role of the jury in applying that law to the facts before it, does not aid the jury in making a decision; rather, it undertakes to tell the jury what result to reach, and thus attempts to substitute the expert's judgment for the jury's.

In re Mirena I, 169 F. Supp. 3d at 413 (S.D.N.Y.), citing and quoting *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991). Rather, a jury needs only testimony and evidence sufficient to evaluate the issue, and such is readily available in the record.

C. The Valenzuela Study[15] Demonstrates There Is A Statistically-Significant Association Between LNG-IUS Use And Intracranial Hypertension

There is no requirement a Plaintiff introduce epidemiological evidence to establish causation.[16] Nonetheless, *supportive* epidemiological evidence is relevant to proving causation. At the *Daubert* stage, Bayer argued for, and this Court adopted, the complete rejection of a peer-reviewed study that has never been criticized in the published literature. That was in error, and this Court's conclusions invaded the province of the jury: "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge." *In re Dana Corp.*, 574 F.3d at 152 (emphasis in original) (citation omitted).

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[15] Reuben M. Valenzuela et al., An Estimation of the Risk of Pseudotumor Cerebri among Users of the Levonorgestrel Intrauterine Device, *Neuro-Ophthalmology*, 2017;41(4):192-97 (hereinafter, "Valenzuela").

[16] See, e.g., *Matrixx Initiatives*, 563 U.S. 27, 39 (2011) ("A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events."); *In re: Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017) ("A causal connection may exist despite the lack of [statistically] significant findings, due to issues such as random misclassification or insufficient power.").

For purposes of this Motion, Plaintiffs raise it again for a simple reason: to enter summary judgment, this Court would have to again reject Valenzuela.

It is not surprising that the Valenzuela does not expressly find causation: "most researchers are conservative when it comes to assessing causal relationships, often calling for stronger evidence and more research before a conclusion is drawn." *Horwin v. Am. Home Prods.*, No. CV 00-04523 WJR (Ex), 2003 U.S. Dist. LEXIS 28039, at *30 (C.D. Cal. May 9, 2003) (quoting The Reference Manual on Scientific Evidence (2Ed. 2000), at 375). The study, however, and its finding of a statistically significant association between a patient's use of an LNG-releasing IUD and the patient having intracranial hypertension, is part of the record this Court must address when deciding summary judgment.

Aside from Bayer's lawyers, Bayer's expert witnesses are the only individuals in the world that have attempted to invalidate Valenzuela based on alleged preferential prescribing. None of these individuals has ever published this opinion, either specifically as a criticism of Valenzuela or otherwise. Significantly, Bayer has never produced any of its own data to support its contention that Mirena is preferentially prescribed to any group:

> MR. JONES: Another thing, your Honor, is there are marketing documents. For instance, one of the issues that you heard injected into kind of the general causation talk by Bayer today was that there's preferential prescribing to women who are overweight. That's something we've heard for months per their experts throughout this. We don't have any sort of sales data that would allow us to make that determination.
>
> HON. PAUL A. ENGELMAYER: What's the relevance of that to a products liability case?
>
> MR. JONES: Because they've made the preferential prescribing relevant because they say that's why so many women are developing PTC; because they're overweight, they're prescribing to more overweight women.
>
> HON. PAUL A. ENGELMAYER: Were they relying, though, on Bayer evidence of the incidence for which the drug was prescribed?

> MR. JONES: We don't know what they're relying on. They just keep saying it in all of their *Daubert* motions without any sort of supporting evidence, and that's what their experts rely on.

ECF 51, Tr. of 06/13/2017 CMC, at 85:19-86:14. For purposes of summary judgment, in the absence of *any* evidence of record supporting "preferential prescribing," much less *indisputable* evidence, this Court cannot hold, as the Court held in its *Daubert* opinion, that there are "preferential prescribing practices" related to Mirena which undermine the data and conclusions of the Valenzuela study. ECF 320, p. 132. If the Court decides (erroneously) that it can simply ignore the testimony of Bayer's expert witnesses, then the Court has *no basis at all*, much less a sufficient basis to create the absence of a genuine dispute, to reject the fact that peer-reviewed literature has established a statistically-significant association between LNG-IUS use and intracranial hypertension.

If the Court reviews the testimony of Bayer's experts witnesses while deciding summary judgment, as it must, this conclusion is bolstered even further. Several of Bayer's proffered experts admitted there is no published data establishing that Mirena is preferentially prescribed to overweight or obese women. For example, Bayer's epidemiology expert Dr. Langer admits there is no data to support the number or percentage of Mirena users in either the United States or Denmark with any specific BMI. *See, e.g.,* ECF 171-2 (quoting Langer Dep. at 27:16-28:13) ("A. **I don't think we have any data to bear on that.** […] I'm not aware of anything other than, you know, individual clinic reports, and **have no idea** of the source of national data."); *and* ("[…] other than looking at individual clinics, like in St. Louis, like in Honolulu, like in Philadelphia, **I am not aware of any national data** for the United States and I'm not aware of any national data for Denmark.") Another of Bayer's experts, Dr. Van Stavern has admitted just as much. *See,* ECF

140-4 (2016 Van Stavern Dep. at 168:18-170:24) ("Q. Do you know what percentage of overweight or obese women in the United States use the Mirena product? A. **I don't know.** I do know that it is."); *and* ("Q. What percentage of Mirena users are overweight obese? A. **I don't have access to that information.**") The numbers were so difficult for Bayer's paid experts to grapple with that one of them re-calculated Valenzuela and then spoliated her data rather than produce it. ECF 166-2 (Newman Dep.), at 200:7-202:11.

These admissions are particularly significant because this Court has apparently concluded that Mirena is preferentially prescribed to overweight and obese women, a conclusion that formed part of its own determination that Valenzuela, which was peer-reviewed, was nonetheless inherently unreliable. *See* 04/10/2018 Tr. of *Daubert* Hearing, at 217:20-220:7 (*i.e.*, "But isn't the fundamental limitations of Valenzuela that the unaccounted-for confounders very substantially define the Mirena universe[…]"); *see also,* ECF 320, p. 9 ("As a result, Mirena is widely believed to be preferentially, i.e., disproportionately, prescribed to overweight and obese women…"); *id.* at p. 132 (criticizing Dr. Johanson for not "consider[ing] any clinical data showing that Mirena users, given the preferential prescribing practices of that contraceptives, are at an increased risk for IIH."). These conclusions were erroneous at the time of *Daubert* and they would be erroneous now, too, for the Court has no basis on which to a decide these conclusions are indisputable facts.

Bayer is free to deny at trial that there is a statistically-significant association between LNG-IUS use and intracranial hypertension. For purposes of summary judgment, however, this Court cannot conclude there is no genuine dispute on this material fact — regardless of whether Plaintiffs have any "general causation" experts or not. Even the cases cherry-picked by Bayer to support their argument concede that a mere differential diagnosis plus supporting epidemiology is

sufficient to prove causation. See, e.g., *Norris,* 397 F. 3d 878, 885 (10th Cir. 2005).

D. Epidemiological Expert Testimony In The Record Opines That The Adverse Event Reporting Rates For Mirena And Intracranial Hypertension Are "Consistent With A Causal Association"

The record in this case shows that adverse event reporting rates are relevant to causation. *See* ECF 174, p. 22, n.33 (citing instances of Bayer's experts relying on adverse event reporting rates for opinions about causation). Bayer's experts brought adverse event reporting rates of intracranial hypertension among Mirena users into their opinions but those experts did not review Bayer's own disproportionality analyses in their Empirica database, which Bayer concealed from Plaintiffs until a designee admitted its existence during her deposition. *See* ECF 174, p. 23. Bayer's epidemiology expert, Dr. Langer, had stated in his report, and subsequently testified, that the adverse event reporting rate supported his opinion that there is *no* causation. When Plaintiffs asked him for his opinions about numbers *lower* than those reflected by Empirica, i.e., a PRR greater than 40 and a Chi^2 greater than 3,000, Dr. Langer agreed those figures "certainly" support causation and "would be consistent with a causal association." ECF 174, p. 24 (quoting Langer Dep. at 188:2-189:22).[17] Thus, in deciding summary judgment, this Court must include in its analysis the presence of expert epidemiological testimony opining that the adverse event reporting rates for Mirena "certainly" support causation and are "consistent with a causal association."

Bayer's Motion makes no mention of Dr. Langer's testimony, despite this issue being raised before in the *Daubert* briefing. Instead, with regard to disproportionality analyses, they cite a smattering of distinguishable cases applying *Daubert* — cases of no relevance here, at summary

[17] *See also,* ECF 174, p. 23, n.37 (citing Manlik Dep. at 22:17-23:2) (defining Bayer's proportionality "threshold" as n greater than or equal to 3, PRR of 2 or more, and Chi^2 of 4 or more).

judgment, where the entirety of the record must be considered and that record includes the entirety of Bayer's experts' testimony — and self-serving testimony from one of their own fact witnesses. ECF 329, pp. 12-13. Neither of these are sufficient to overcome the simple fact that, on this record, there is a genuine dispute of the material fact that the adverse event reporting rates of intracranial hypertension among Mirena users are consistent with a causal association.

1. Bayer Cannot Use Etminan To Support Summary Judgment

This Court's *Daubert* order concludes that "the surviving half of the Etminan study (which compared Mirena with oral contraceptives) did not find any such increased risk." ECF 230, p. 37. This factual conclusion by the Court was already erroneous and unsupportable for purposes of *Daubert*; for purposes here, this same erroneous factual conclusion cannot be used to support entering summary judgment. Peer-reviewed literature found the methodology of that "surviving half" to be "egregious" and riddled with methodological errors.[18] Moreover, as Bayer's expert epidemiologist Dr. Langer admitted, there is no "surviving half" of Etminan, and the study is not a reliable basis to form any conclusions at all:

> Q. Dr. Langer, do you believe the Etminan 2015 paper is a reliable basis to conclude that there is no difference in the risk of IIH for users of Mirena versus users of oral contraceptives containing progestins other than LNG?
> A. I don't believe it's a reliable study.
> Q. So it's not a reliable basis to conclude there is no difference in the risk of IIH for users of Mirena versus users of oral contraceptives containing progestins other than LNG?
> A. Yes, that's correct.

ECF 171, p. 6 (quoting Langer Dep. at 124:5-124:15). Thus, for purposes of summary judgment, the record here contains a genuine dispute of material fact as to whether the Etminan study is a

[18] See ECF 174, § IV(A), pp. 10-12, discussing same.

reliable basis for drawing any conclusions about a causal association between Mirena use and intracranial hypertension.

Furthermore, as objected to by Plaintiffs in the *Daubert* motions (ECF 213, p. 12; ECF 213-6) yet relied upon heavily by the Court without analysis in its *Daubert* order (ECF 320, pp. 23, 26-28, 72-74, 104), the Etminan "Affidavit" cannot be presented in a form that would be admissible in evidence and thus was both impermissibly used in deciding *Daubert* and cannot be considered at summary judgment. Fed.R.Civ.P. 56(c)(2). Dr. Etminan has never been an expert in this litigation and he was not an expert for *any* Mirena user *at all* at the time of the *ex parte* "Affidavit." The contents of the "Affidavit" are thus classic hearsay and no exception applies. The Etminan Affidavit cannot be a prior statement under F.R.E. 801(d)(1), because it was not testimony and Etminan was not subject to cross-examination. Etminan similarly was not unavailable under F.R.E. 804 to be called to testify in this action. Bayer's experts themselves cannot rely upon it: most materials that experts rely on fall within F.R.E. 803(18), but the Etminan Affidavit is not "a statement contained in a treatise, periodical, or pamphlet," nor has anyone testified about it being published by a "reliable authority."

For purposes of summary judgment, Etminan does not exist: on this record, there is no way for the Court to utilize the study, the letter to the editor, or the "Affidavit" to find the absence of a genuine dispute of any material fact. Even if the Court attempted to rely on the "Affidavit" for summary judgment, it would run straight into another admission by Bayer itself: Bayer's employees admitted the Affidavit "never retracts his previously published analyses/conclusions or says they were inaccurate." ECF 213-6, p. 2, quoting MIR_IIH_EU01163621.

E. The Evidence Establishes A Biological Mechanism That Is More Than Sufficiently Developed To Be Presented To A Jury

There is no requirement a Plaintiff prove a biological mechanism to establish causation. "[C]ausation can be proved even when we don't know precisely how the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage somehow."[19] Nonetheless, evidence of a plausible biological mechanism is relevant to general causation. Bayer itself has admitted it has not designed a study to measure whether a connection between Mirena and PTC/IH is biologically plausible. ECF 326, #21.

As with all of Bayer's arguments about admissions, Bayer improperly tries to narrow the scope of relevant admissions, as if only an explicit concession would be admissible: "*none* of Plaintiffs' cited pieces of evidence constitutes an admission that a biological mechanism exists by which Mirena can cause IIH." ECF 329, p. 18. There is no need or requirement for Plaintiffs to produce such an admission. The issue in this Motion is if any Plaintiff could come forward with sufficient evidence to show a genuine dispute of material fact regarding causation. To put it another way, could a Plaintiff use those admissions plus the testimony of their witnesses, including their case-specific experts, to establish causation? The answer on the whole is "yes," and, in this section, Plaintiffs focus on the admissions relevant to biological mechanism that could be used to prove causation in their particular case.

Although no *definitive* mechanism for PTC/IH has been established, for purposes of summary judgment, sex hormones are intrinsically connected to its pathophysiology. Bayer admits LNG is a potent synthetic progestin, a form of reproductive hormone. ECF 326, #56. Bayer admits

[19] *Lyman v. Pfizer, Inc.*, No. 2:09-CV-262, 2012 WL 2971550, at *3 (D. Vt. July 20, 2012) (quoting *In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1247 (W.D. Wash. 2003)); *accord Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1236-37 (9th Cir. 2017) ("Causation can be proved even when we don't know precisely how the damage occurred, if there is sufficiently compelling proof that the agent must have caused the damage somehow." (citation omitted).

peer-reviewed literature recognizes a link between reproductive hormones and PTC/IH. ECF 326, #34. Bayer's experts Dr. Bruce and Dr. Newman admit, in the published scientific literature, the likely role of sex hormones in PTC/IH pathophysiology. ECF 187-7 (2010 Thurtell *et al.*, p. 6); ECF 187-8 (2010 Fraser *et al.*, p. 88). Bayer admits peer-reviewed literature recognizes drug-induced PTC/IH. ECF 326, #32. Bayer's expert Dr. Van Stavern admits published studies associate hormonal agents with PTC. ECF 326, #111. Bayer's expert Dr. Dinkin admits published scientific literature recognizes "secondary IIH induced by a medication." ECF 326, #113.

Bayer's own filings with regulatory authorities state, and thus admit, how two-thirds of cerebrospinal fluid (CSF) is produced by the choroid plexus. ECF 167-71, p. 11. Bayer admits peer-reviewed literature has identified at least three plausible mechanisms by which PTC/IH develops, including increased CSF production, reduced CSF drainage due to increased venous sinus pressure, and reduced CSF drainage due to increase outflow resistance. ECF 326, #31.

Bayer's pharmacology expert Dr. Jusko admits sufficient LNG released by Mirena reaches the brain to "suppress the hypothalamic-pituitary-ovarian axis[.]" ECF 135, p. 3 (quoting Jusko Dep. at 203:22-205:2). Bayer has admitted LNG can cross the blood-brain barrier or the blood-CSF barrier, can reach the choroid plexus region, and can be found in the choroid plexus region. ECF 326, #48-#51. Bayer's expert Dr. Barnhart admits Mirena can cause androgenic effects, and admits "levonorgestrel can interact with other receptors." ECF 326, #77. Bayer admits LNG has been shown to bind to the mineralocorticoid receptor, ECF 326, #26, and that peer-reviewed literature includes "theories around stimulation of the choroid plexus via actions of endogenous or exogenous substances on the mineralocorticoid receptor." ECF 167-71, p. 12.

Thus, for purposes of summary judgment, the Court must accept LNG is a reproductive

hormone, reproductive hormones are linked with PTC, PTC can be induced by medications, CSF is produced by the choroid plexus, peer-reviewed literature includes mechanism of PTC involving CSF, LNG reaches the brain, crosses the blood-brain and blood-CSF barriers, is capable of causing changes in the brain, is capable of engaging reproductive hormone receptors for androgens, is capable of causing reproductive hormone side effects, is capable of binding to mineralocorticoid receptors, and that peer-reviewed literature recognizes a potential link between those same receptors, in the same region of the brain (the choroid plexus), and causing PTC.

These are not scattered assertions of counsel, they are admitted facts, and they present a more thorough mechanism than is typically found in mass torts, with specificity down to the receptors in a particular region of the brain. Any Plaintiff in this case can come into Court and present those facts as part of their proof of causation. These admitted facts do not require a supporting expert to present them to the jury, but a Plaintiff *could* retain a case-specific expert who then utilizes these admissions in their own opinion.

F. The FDA Has Determined That Levonorgestrel Is Capable Of Causing Intracranial Hypertension

The prescribing information for FDA-approved products includes two separate sections on potential side effects, the "Warnings and Precautions" and the "Adverse Reactions." A Warning or Precaution must be added when there is "reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6).[20] As Bayer itself is arguing to the Supreme Court in a pending case, when the FDA considers a safety issue and reaches a conclusion about adding or rejecting a

[20] The Adverse Reactions standard is lower, but not unbounded. A manufacturer must add "only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event." 21 C.F.R. § 201.57(c)(7).

Warning, the FDA's decision inherently reflects a determination that, respectively, there is or is not "reasonable evidence of a causal association." In this case, the FDA has never considered if a Warning for intracranial hypertension should be added to Mirena (because Bayer has never presented the issue to the FDA) and so no conclusions can be drawn either way, but the FDA *has* considered a Warning for intracranial hypertension and other levonorgestrel products. The inclusion of a Warning on these products, such as Jadelle, reflects the FDA's determination that levonorgestrel is capable of causing or contributing to intracranial hypertension. This determination by the FDA is, by itself, more than sufficient to demonstrate a genuine dispute on the material fact of general causation.[21]

The Warnings and Precautions for Jadelle, an FDA-approved implant manufactured by Bayer (and for which Bayer is the "sponsor" of the drug for purposes of FDA regulation) that has the sole active ingredient of levonorgestrel, include:

> 5.9 Idiopathic Intracranial Hypertension
>
> Idiopathic intracranial hypertension has been reported on rare occasions in users of levonorgestrel implants. Consider this diagnosis if persistent headache and/or visual disturbances occur in a woman with JADELLE, particularly if the patient is obese or has recently gained weight. Remove JADELLE if idiopathic intracranial hypertension is diagnosed.[22]

Bayer's motion focuses on the language "reported", to argue the labeling has no relationship to causation, but that misses the forest for the trees. The inclusion of intracranial hypertension on the

[21] As mentioned throughout this memorandum, Bayer's Motion makes no effort to define "general causation." It is Bayer's burden to explain the law it asks this Court to apply, and Plaintiffs' use of various potential standards for coherence is not a waiver of their objection to the entire process of being forced to guess about the substantive content of a movant's argument for summary judgment.

[22] Publicly available at:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020544s010lbl.pdf

Jadelle label reflects the FDA's determination that levonorgestrel is capable of causing intracranial hypertension. If the FDA did not determine that levonorgestrel was capable of causing intracranial hypertension, then the "reasonable evidence of a causal association" standard would not be met, and the FDA would be obligated to remove that language.

Bayer itself is currently making the same argument to the Supreme Court, via an industry association it is a member of and the same counsel it has in this MDL:

> The FDA must approve labeling before a medicine can be marketed, and the agency continues to scrutinize labeling for as long as the medicine remains on the market. **While the manufacturer bears responsibility for its labeling, the FDA is the final authority on its contents**. Before a manufacturer can amend its labeling, it generally must obtain FDA approval through the submission of a "prior approval supplement" ("PAS") to its New Drug Application. See 21 C.F.R. § 314.70(b)(2)(v). Manufacturers can, in some circumstances, add or strengthen a warning to reflect "newly acquired information." See id. § 314.70(c)(6)(iii). Even then, however, a manufacturer cannot distribute the new labeling until it submits a "changes being effected" ("CBE") supplement to the FDA. See id. § 314.70(c)(3)–(6). Once a CBE supplement is submitted, the FDA must review the contents of the amended labeling, and **if the FDA does not find that "the evidence of a causal association satisfies the standard for inclusion in the labeling," id. § 314.70(c)(6)(iii)(A), it must retroactively reject the change** and may order the manufacturer to stop distributing products with the new labeling, see id. § 314.70(c)(6)–(7); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49,603, 49,608 (Aug. 22, 2008) ("[A] CBE supplement may be used to add or strengthen a contraindication, warning, precaution, or adverse reaction **only if there is sufficient evidence of a causal association with the drug** . . . ."). In all circumstances, then, the FDA is the final arbiter of the contents of new and amended drug labeling.

Amici Curiae Brief of Pharmaceutical Research and Manufacturers of America, et al., pp. 7-8 (emphases added), filed on September 20, 2018, in *Merck Sharp & Dohme Corp. v. Albrecht*, No 17-290. Bayer knew Plaintiffs would raise this issue, see ECF 326, p. 2, but Bayer's Motion does not address it at all.

Instead, Bayer's Motion first reminds this Court how defective the record is in this case: "Jadelle is a different product with a different regulatory history than Mirena, and its label is the result of data and regulatory interactions not before this Court." ECF 329, p. 13. Plaintiffs are well-aware Jadelle's regulatory history is not before this Court, because Plaintiffs sought it at the onset of this litigation, Bayer objected, and this Court denied it. But that gap in the record does not help Bayer: as Bayer itself told the Supreme Court, the Warnings and Precautions section of the Jadelle label can include intracranial hypertension "only if there is sufficient evidence of a causal association with the drug." As Bayer itself argued, if the FDA had found that the evidence of a causal association did not satisfy the standard for inclusion in the labeling, the FDA would have been obligated to remove it. The Warning itself demonstrates, as a matter of law, the FDA's findings. Bayer cannot evade the consequences of its own legal argument by claiming that, buried in a regulatory file it refused to produce, there are "regulatory interactions" that would somehow change the FDA's statutory and regulatory framework.

Otherwise, Bayer's Motion makes the banal point that labeling, by itself, cannot prove a particular Plaintiff's injury was caused by a drug. That may be so, but that point is irrelevant here, where there is ample other evidence, and that point is an issue for case-specific motions. For purposes of "general causation," however that may be defined, the FDA has determined levonorgestrel is capable of causing intracranial hypertension. Similarly, Bayer's arguments about the differing LNG serum levels of Jadelle and Mirena might be relevant to Bayer's defense at trial, but they are of no use to Bayer on a motion for summary judgment on general causation. Moreover, the record is replete with admissions by Bayer about the wide variability and interactions of LNG in the blood serum of Mirena users, as well as the existence of patients sensitive to its effects and

to PTC specifically. *See, e.g.*, ECF 326, #4-#6, #28, #52, #54-#55, #58-#62, #74, #78-#80, #117. The Court must accept those admitted facts at summary judgment, and must thereafter make inferences in Plaintiffs' favor.

As argued by Bayer, the FDA's determination that there is "reasonable evidence of a causal association" between levonorgestrel and intracranial hypertension is not a matter of discretion, but an affirmative duty of the FDA under its relevant statutes and regulations: "[a]s explained above, where the FDA has determined, considering the scientifically-based evidence at its disposal, that new safety information warrants a warning, it has an affirmative duty to add information to the labeling about that risk using Section 505(o)(4)." *Id.* at 16. "In no circumstance can the FDA determine that an unlabeled safety risk requires a warning, yet do nothing. To do so would violate the FDA's duty under Section 505(o)(4)." *Id.* For purposes of summary judgment, the Court must accept the FDA has determined levonorgestrel is capable of causing or contributing intracranial hypertension — and Bayer cannot argue otherwise.

V. SUMMARY JUDGMENT IN THIS CONTEXT IS INHERENTLY UNCONSTITUTIONAL

The Seventh Amendment provides:

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules of the common law.

"Dollars," as understood by the public at the time,[23] would refer to a Spanish silver dollar, also known as a "piece of eight," which Alexander Hamilton determined weighed an average of 27

[23] *See* The Coinage Act of April 2, 1792, 1 Stat. 246 § 9 (1792) (enabling Congress to coin "dollars or units—each to be the value of a Spanish milled dollar."); H.R. Rep. No. 23-278 at 65 (1834) (noting the Articles of Confederation Congress used the Spanish silver dollar standard in 1786); see also Sumner, The Spanish Dollar and the Colonial Shilling, 3 AMER. HIST. REV. 607 (1898).

grams, also known as a "piece of eight," and the Coinage Act of 1792 established the same as a "dollar."[24] Every case in this MDL has a value in controversy exceeding 540 (27 × 20) grams of silver ($270).

At the time the Seventh Amendment was ratified, there was no procedure "according to the rules of the common law" in which a court could look at both parties' evidence and decide whether a reasonable jury could find for the nonmoving party, examining only inferences that a judge deems reasonable.[25] None of the procedures "according to the rules of common law," such as the demurrer to the pleadings, the demurrer to the evidence, the nonsuit, the special case, and the new trial, enabled to determine who should win if it believed the evidence was insufficient. Put another way, "a modern judge who is committed to interpreting the Seventh Amendment as its drafters and ratifiers would have applied it should deem summary judgment and the *Twombly* motion to dismiss unconstitutional."[26] This subject of what the Seventh Amendment meant to its drafters and ratifiers is not a question solely for idle scholars; it is a routine method of constitutional interpretation by the Supreme Court. *See, e.g., District of Columbia v. Heller*, 554 US 570 (2008)("In interpreting this text, we are guided by the principle that '[t]he Constitution was written to be understood by the voters; its words and phrases were used in their normal and ordinary as distinguished from technical meaning.'" (Quoting *United States v. Sprague*, 282 U.S.

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[24] Shepard Pond, *The Spanish Dollar: The World's Most Famous Silver Coin,* 15 BULLETIN OF THE BUSINESS HISTORICAL SOCIETY 12–6. (1941).

[25] Thomas, Suja A., Why Summary Judgment is Unconstitutional. Virginia Law Review, Vol. 93, p. 139, 2007; University of Cincinnati Public Law Research Paper No. 06-04. Available at SSRN: https://ssrn.com/abstract=886363.

[26] William E. Nelson, Summary Judgment and the Progressive Constitution, 93 IOWA L. REV. 1653 (2008).

716, 731, (1931))); *see also Lucia v. SEC*, 138 S. Ct. 2044, 2056 (2018) (Thomas, J., and Gorsuch, J., concurring) ("I would resolve that question based on the original public meaning…").

There is no need at this juncture for a wholesale declaration that summary judgment is unconstitutional in all cases. Rather, Plaintiffs *here* raise the issue in *this* context, in which the proceedings thus far have been wholly removed from any individual Plaintiffs' evidence, and in which Bayer can only have summary judgment entered in its favor upon this Court reaching the *factual conclusion* that the levonorgestrel in Mirena could not have caused any of the Plaintiffs' intracranial hypertension. Even jurists who find summary judgment constitutional recognize that would exceed the limitations imposed by the Seventh Amendment:

> [S]ince we deal here not with the common law *qua* common law but with the Constitution, no amount of argument that the device provides for more efficiency or more accuracy or is fairer will save it if the degree of invasion of the jury's province is greater than allowed in 1791. To rule otherwise would effectively permit judicial repeal of the Seventh Amendment because nearly any change in the province of the jury, no matter how drastic the diminution of its functions, can always be denominated "procedural reform."

Parklane Hosiery Co. v. Shore, 439 US 322, 346 (1979)(Rehnquist, J., dissenting).

CONCLUSION

Summary judgment can be entered, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case. None of those conditions are met here, and so summary judgment cannot be entered.

As movant, Bayer has the initial burden of persuasion. Bayer knew Plaintiffs' position upfront: "general causation is not an essential element to any of the State-law causes of actions raised by any of the Plaintiffs." ECF 326, p. 2 (citing Restatement (Third) of Torts). Despite that, Bayer did not attempt to establish "general causation" was an "essential element" of Plaintiffs'

state law causes of action. Instead, Bayer briefly referenced a handful of federal cases and then dumped on the Court a 10-page single-spaced "Appendix" that contained with no argument whatsoever, was riddled with cases that do not support their argument, and omitted key cases contrary to their argument. Bayer did not even attempt to define "general causation," much less elaborate on what sort of evidence could establish that "essential element" yet was lacking from Plaintiffs' case. This Court need not go farther; it can and should simply deny the motion on that basis.

If the Court does go farther, it will find no path to summary judgment. This Court has precluded the development of a record on the actual issue raised by Bayer's motion, which is whether Plaintiffs could produce evidence sufficient to establish causation under their respective states' laws. The *Daubert* order, unmoored from any substantive law, cannot be squared with the substantive law of causation in any state, much less all of them. The Plaintiffs have had no opportunity to produce the evidence actually required by state substantive law, which is case-specific proof their Mirena caused *their* injuries. That would be a problem in any case, but it is a uniquely prejudicial problem in this case, given that the injury suffered by Plaintiffs *and its cause* are typically diagnosed by an inherently case-specific process, the differential diagnosis.

These problems would persist even if this Court accepts Bayer's invitation to cast aside the *Erie* doctrine and the Rules Enabling Act to create a federal element of "general causation" that has no definition and supplants substantive state tort law. Yet, even *that* absurd result would still not warrant the entry of summary judgment, because the available evidence — drawn from Bayer's admissions, Bayer's experts, peer-reviewed literature, medical guidelines, and the FDA itself — is more than sufficient for a jury to conclude levonorgestrel is capable of causing or contributing to

intracranial hypertension and thus satisfy the supposed element of "general causation." Bayer's motion must be denied.

Dated: January 18, 2019

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing was filed via the ECF/CM system with the Clerk of the Court, which will have sent notice to all attorneys of record in this matter on January 18, 2019.

/s/ Lawrence L. Jones II
Lawrence L. Jones